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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,157	06/15/2006	Antonello Pietrangelo	8907-109-999	7977
20583	7550	09/09/2009		
JONES DAY 222 EAST 41ST ST NEW YORK, NY 10017			EXAMINER GOLDBERG, JEANINE ANNE	
			ART UNIT 1634	PAPER NUMBER
			MAIL DATE 09/09/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

**Office Action Summary****Application No.**

10/560,157

**Applicant(s)**

PIETRANGELO, ANTONELLO

**Examiner**

JEANINE A. GOLDBERG

**Art Unit**

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 August 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1.4.11-14, 16, 18-21 and 50-52 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1.4.11-14, 18-21 and 50-51 is/are allowed.
- 6) ☒ Claim(s) 16 and 52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. This action is in response to the papers filed August 27, 2009. Currently, claims 1, 4, 11-14, 16, 18-21, 50-53 are pending. Claims 1, 4, 11-14, 18-21, 50-51 are allowable.
2. Claims 16 and 52 are rejected.
3. All arguments have been thoroughly reviewed but are deemed non-persuasive for the reasons which follow.
4. This action contains new grounds of rejection.
5. Any objections and rejections not reiterated below are hereby withdrawn.
  - a. The enablement, written description and 112/2<sup>nd</sup> rejections have been overcome in view of the amendments to the claims and arguments presented.

***Election/Restrictions***

6. Applicant's election with traverse of Group I, Claims 1-4, 11-21, 50-52 in the paper filed July 8, 2008 is acknowledged.

The response asserts that there would be no burden to search Groups I-III together, citing 803. The response asserts that each mutation comprises a single nucleotide substitution of SEQ ID NO: 2 and is associated with non-HFE hemochromatosis. This argument has been reviewed but is not persuasive. This application was filed under 371 and considers whether there is a single inventive concept which links the inventions. Here, as noted in the initial lack of unity requirement, claims drawn to 10 nucleotides do not make a contribution over the art.

Furthermore, Group I, II and III are directed to mutations in the ferroportin 1 gene. Mutations within the ferroportin 1 gene were known in the art at the time the invention was made, including A77D. Thus, there is no special technical feature which links the inventions and Groups I, II, and III will not be rejoined.

Claims 5-10, 22-49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the paper filed July 8, 2008.

The requirement is still deemed proper and is therefore made FINAL.

This application contains Claims 5-10, 22-49 drawn to an invention nonelected with traverse in the paper filed July 8, 2008. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

### ***Priority***

7. This application is a 371 of PCT/EP04/51068, filed June 9, 2004. The application also claims priority to ILALY MI2003A001156, filed June 9, 2003.

It is noted that a translation of the foreign document has been received on February 26, 2009.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 16 and 52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claim 16 is indefinite. The claim requires an isolated polynucleotide comprising more than 10 consecutive nucleotides of SEQ ID NO: 3. It is unclear whether the isolated polynucleotide comprises more than 10 consecutive nucleotides of SEQ ID NO: 3 where the 10 nucleotides comprises position 238 of SEQ ID NO: 3 and comprises at least one of SEQ ID NO: 13 or 14. Or, whether the claim merely requires at least 10 consecutive nucleotides of SEQ ID NO: 3, an A or G and SEQ ID NO: 13 or 14. It is unclear what is meant by the isolated polynucleotide comprises position 238. It is unclear whether this means the claimed polynucleotide only comprises an A or G or whether there is some context required for the claimed polynucleotide.

b. Claim 52 is indefinite because the metes and bounds of the claimed invention are unclear. The claim appears to be directed to a kit comprising at least one of the oligonucleotides of sequence: SEQ ID NO: 13, or 14. It is unclear whether the oligonucleotides may be within a larger sequence, i.e. comprising or whether the claim is limited to a nucleic acid consisting of SEQ ID NO: 13 or 14.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claim 52 is rejected under 35 U.S.C. 102(e) as being anticipated by Venter et al. (US Pat. 6,812,339, November 2, 2004).

In view of the 112/2<sup>nd</sup> rejection above, it is unclear whether the claims are directed to a nucleic acid comprising SEQ ID NO: 13 or 14 or whether the claim is limited to a nucleic acid consisting of SEQ ID NO: 13 or 14. The rejection below is provided in the event that the claims are directed to comprising SEQ ID NO: 13.

Venter teaches kits comprising nucleic acids. Venter teaches a nucleic acid comprising SEQ ID NO: 13.

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Query Match          100.0%;  Score 23;  DB 3;  Length 601;
Best Local Similarity 100.0%;  Pred. No. 0.21;
Matches 23;  Conservative 0;  Mismatches 0;  Indels
0;  Gaps 0;

Qy          1  CATAATGTAGCCAGGAAGTGCCC 23
             |||||||||||||||||||||
Db          99 CATAATGTAGCCAGGAAGTGCCC 77
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### ***Conclusion***

**10. No claims allowable.**

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (571) 272-0743. The examiner can normally be reached Monday-Friday from 7:00 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz, can be reached on (571)272-0763.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

The Central Fax Number for official correspondence is (571) 273-8300.

**/Jeanine Goldberg/**  
**Primary Examiner**  
September 9, 2009